

Questions and Answers about “Policy regarding Management of Conflict of Interest (COI) in Health and Labour Science Research”

*These questions and answers will be reviewed (including additions and revisions) accordingly to conform to the present conditions.

Q1 Does the “economical interest” include free provision of goods and services, etc.?

A1 The “economical interest” includes all things that have some monetary value. Accordingly, free provision of goods and services, etc. is included in the “economical interest”.

Q2 Do cases such as a case where a company provides products of the company without any compensation in support of the purpose of clinical research, etc. fall under the “economical interest” of the researcher?

A2 It is necessary to judge whether an action is considered to be the “economical interest” provided to the researcher or one kind of provision of external funds, etc. for the research, based on conditions of free provision (including contents of a contract, etc.). Accordingly, it is necessary to accurately report a relationship with the company (including the contents of the contract and other economical interests) to the COI committee of the researcher’s organization and take appropriate control measures based on judgements of the COI committee. In the meantime, in both of the case where the action is considered to be the economical interest provided to the researcher and the case where it is considered to be one kind of provision of external funds, etc. for the research, it is necessary to explain that collaboration of the company has been gotten when explaining funding sources, etc. to the subject based on the Helsinki Declaration and the ethical guidelines for clinical research.

Q3 In a case where measures based on the ”Guidelines for Setting COI policy in Clinical Research” presented in the ”Model Program for Construction of Academic-Industrial Collaboration Method in the 21st Century” of the Ministry of Education, Culture, Sports, Science and Technology have already been taken in the researcher’s organization, are new measures necessary?

A3 Basically, if the measures based on the ”Guidelines for Setting COI policy in Clinical Research” have been taken appropriately in the researcher’s organization, such measures are considered to meet not only clinical researches but also this policy.

Q4 Is this policy applicable to researches other than those of public application type (designation type and strategy type, etc.)?

A4 This policy is applicable to health and labour science researches in general, and confirmations, etc. of conditions of the COI management are scheduled to be made also in connection with researches of

designation type from the fiscal year of 2008. In the meantime, in cases where the researcher's organization is not ready in the fiscal years of 2008 and 2009, necessary information is obtained from the researcher and a review of the COI management is scheduled to be conducted by the Ministry of Health, Labour and Welfare in connection with researches of designation type.

Q5 In case of health and labour science researches other than clinical researches (for example, social science research subjects), are a report of the economical interest to the COI committee and an application for examination unnecessary?

A5 In case of health and labour science researches (not limited to clinical researches), the COI management such as an application for examination to the researcher's organization, etc. is necessary.

Q6 Although the examination of the COI is to be applied to the COI committee of the researcher's organization, etc. by the time of submitting a request for the health and labour science research grant, is an examination result of the COI committee to be accompanied with the application or to be reported at a later date?

A6 Although the COI management is to be appropriately implemented by the researcher's organization and the examination of the COI committee is required to be concluded as early as possible, it is not necessary to submit the examination result at the time of submitting the request for the grant. In the meantime, whether or not the application for the examination to the COI committee, etc., etc. is scheduled to be confirmed, and the conditions, etc. of the COI management are scheduled to be required to be reported in a business performance report at the time of submitting the request for the grant. Also, although the Ministry of Health, Labour and Welfare or the allocation organization may conduct a search on the COI when considered to be necessary, it is necessary to provide the examination result of the COI committee at that time.

Q7 How many years ago is the "economical interest" from? Although the relevant documents of the COI are to be preserved for 5 years, is any funding of 5 years or more considered to be outside the scope of the management?

A7 The "economical interest" during the health and labour science research is supposed to be reported to the COI committee of the researcher's organization every fiscal year. In the policy, a standard of reporting for this "economical interest" may be set in view of actual circumstances of each organization, and it is possible to set a standard to the effect that the economical interest of not only the fiscal year at issue but also the past few years is to be reported based on judgements of the COI committee of the researcher's organization, etc.. Also, the relevant documents of the COI are to be preserved for 5 years, and this period means a preservation period after the COI management. It is to be fully noted that implementing the COI management in full consideration of relevant circumstances for each individual case

is considered to be appropriate, and in cases where various conditions overlap, there is a possibility that a harmful influence is pointed out to occur from the outside even if such conditions do not fall under the standard of reporting. Because of this, in cases where a large donation was made by a certain company 5 years ago or more and a health and labour science research closely related to interests of the company is implemented, it is necessary to act very carefully (for example, to actively consult with the COI committee) in order not to give an impression that fairness and objectivity of the health and labour science research are undermined.

Q8 Is a relationship with a company that made a large donation 2 years ago unnecessary to be reported to the COI committee?

A8 Each organization sets the standard of reporting to the COI committee, the researcher shall observe it, and periods, etc. are also set by each organization. Also, even in cases where an action does not conflict with the standard set by each organization, it is necessary to exercise an appropriate management (for example, to request the COI committee of the researcher's organization to review measures of the COI management), when it is concerned that a third party has the impression that the fairness and objectivity of the health and labour science research are undermined.

Q9 When is the economical interest considered to be a "case where it does not conflict with the standard set by each researcher's organization, but a possibility that a harmful influence seems to occur is concerned from the outside"?

A9 In cases where the economical interest with the company does not conflict with the standard set by the organization, but the possibility that the harmful influence seems to occur is concerned from the outside in perspective, the appropriate management (for example, requesting the COI committee of the researcher's organization to review the measures of the COI management) is necessary to be exercised.

For example, a case where at the time of implementing a research related to a pharmaceutical product, a visiting researcher comes from a company that produces the pharmaceutical product to a laboratory to which the researcher belongs, etc. fall within the scope.

Q10 Although II2 stipulates that rewards, etc. supplied from public organizations are not included in the "economical interest", is it right to understand that since public service corporations which aim at promoting researches such as granting research expenses, etc. can be considered to be handled equally with the public organizations from their public interest, a research grant offered from these corporations is not included in the "economical interest" as falling under the rewards? Also, is it right to understand that incorporated administrative agencies (Japan Society for the Promotion of Science and JST, etc.) are public organizations?

A10 The research grant and commission supplied from the public organizations and the public service corporations do not fall within the scope of the rewards (and therefore, are included in the “economical interest”). The “public organizations” include national and local governments and the incorporated administrative agencies. For example, the rewards at the time of giving a lecture in the incorporated administrative agencies do not fall within the scope of the “economical interest”, but the research grant and commission supplied from the incorporated administrative agencies fall within the scope of the “economical interest”. (Since there is a case where those are considered to be an amount received regarding academic-industrial collaboration activities, measures such as actively consulting with the COI committee, etc. are to be taken.)

Q11 Is it right to understand that rewards for a lecture supplied from learned societies fall within the scope of the rewards supplied from the public organizations, and therefore are not included in the economical interest?

A11 The learned societies do not fall within the scope of the public organizations, and therefore the rewards for the lecture supplied from the learned societies are included in the “economical interest”. Also, there may be a case where it is appropriate to include rewards supplied from the learned societies in the economical interest from a certain company, when the certain company is a sponsor.

Q12 Does not the Ministry of Health, Labour and Welfare confirm establishment of the COI committee of each organization? Are advanced registration, etc. unnecessary?

A12 Although confirming that the application for the examination of the COI to the COI committee of the researcher’s organization, etc. and requiring a report of the conditions, etc. of the COI management in the business performance report are scheduled at the time of submitting the request for the grant, and conducting a search on methods, etc. of the COI management of each organization is scheduled when necessary, the advanced registration, etc. are not scheduled to be required for the time being.

Q13 What is referred to when amounts of the economical interest to be reported to the COI committee are exemplified?

A13 Examples of the “Guidelines for Setting COI policy in Clinical Research” presented in the “Model Program for Construction of Academic-Industrial Collaboration Method in the 21st Century” of the Ministry of Education, Culture, Sports, Science and Technology are referred to, and the amounts of the economical interest are in accordance with such examples.

Q14 Is it right to understand that regarding consigned research funds from the public service corporations, it is not appropriate to treat cooperative researches by the public and private sectors equally

with an entrustment from one company to one research institute and therefore are not included in donations from companies?

A14 They are not the donations from the companies, but fall within the scope of the amounts received regarding the academic-industrial collaboration activities. Also in connection with the research expenses from the public services corporations, the COI management is to be appropriately exercised in view of their nature, etc..

Q15 Is it right to understand that in cases where the researcher is a flexible researcher from a foundation, and fiscal resources are paid by the national government, this policy is not applicable?

A15 Even if the fiscal resources are paid by the national government, this policy is applicable as in the same manner as subsidies, etc. from other foundations.

Q16 What kind of action is to be taken when a director of a research organization receives the health and labour science research grant as a researcher?

A16 It is necessary to establish a “delegation” provision regarding the COI management as a provision of the researcher’s organization, and take measures such as entrusting performance of a duty regarding the COI management to other person, etc. when the director of the organization implements the health and labour science research as a researcher.

Q17 Although V stipulates that “the Ministry of Health, Labour and Welfare or the allocation organization may conduct a search on the researcher’s organization, what will happen when such a search is refused?

A17 In the public offering guide of the health and labour science grant of the fiscal year 2008, the “points of attention regarding research ethics at the time of formulating a research protocol” stipulate that ethical guidelines, etc. set by each government ministry are to be observed, and understanding in advance that a search on observance conditions thereof is conducted in some cases is required. Also, it is stipulated that the COI is under examination of a review committee, and handlings thereof will be published at a later date. In the meantime, it is also explicitly stipulated that measures such as a cancellation of an adoption, a cancellation of a grant notification of subsidy, and a refund etc. are taken in some cases when a research project is implemented in violation of the public offering guide, and there is a possibility that these measures are taken when the search is refused without justifiable reasons.

Q18 Although V stipulates that “the Ministry of Health, Labour and Welfare or the allocation organization may conduct a search on the researcher’s organization , is not there a case where the Ministry of Health, Labour and Welfare conducts the search when the grant is received from the allocation organization?

A18 Members of not only the allocation but also the Ministry of Health, Labour and Welfare may participate in the search.

Q19 When calculating amounts received by the researcher, is it possible that they are considered to be substantial amounts received by an individual researcher without being included in amounts received as a director of an organization or a division (as an addressee)?

A19 Although basically all the amounts received by the researcher are to be summed up, it is possible to set a certain rule in the researcher's organization, and separately calculate some amounts when it is clear that they are not directly relevant with the researcher. In the meantime, it is considered that there is a case where some amounts are to be summed up to the contrary in a case of a substantial beneficiary rather than a receiving nominee, and handlings are to be decided after a review of the COI committee of the researcher's organization when there is a doubt.

Q20 What action is to be taken when there is no COI committee in an organization to which a research member belongs?

A20 An appropriate COI management is necessary also in a case of the research member. In a case where the organization to which the research member belongs is small sized and therefore it is not possible to establish a COI committee, please ask an organization, etc. of the chief researcher to examine and review the COI management of the research member.

Q21 Is it possible to make an ethical review committee of the researcher's organization double as a COI committee?

A21 The director of the research organization may make a committee already established in the organization such as the ethical review committee double as the COI committee. Also, it is possible to establish a subcommittee, etc. under the COI committee and make it examine and review the COI.

Q22 Is it possible to appoint a professor of other faculty of a same university as an outside member of the COI committee?

A22 It is not considered that a person belonging to the organization in a same corporation or the researcher's organization of which director (a person establishing the COI committee) is common, etc. is regarded as an "outsider". Also, appointing a person belonging to an organization in a manner that is not regarded as an outsider in terms of common sense (for example, an organization that rents a room in a same facility and is closely related to the researcher's organization) as the outside member is to be avoided.

Q23 Are measures such as a cancellation of funding, etc. also to be taken against the chief researcher when the research member exercises an inappropriate COI management?

A23 Even if the COI management of the research member is inappropriate, it is not highly likely that the measures such as the cancellation of funding, etc. are taken against the chief researcher, when it is not recognized that the chief researcher is responsible for that. However, each individual case is judged after confirming conditions of involvement of the chief researcher and conditions of the COI management of the research as a whole, etc..

Q24 When the COI management is inappropriately exercised and the measures such as the cancellation of funding, etc. are taken, is the researcher's organization as a whole subject to such measures?

A24 The measures such as the cancellation of funding, etc. are judged after conducting a search on an individual research. However, when there is a problem with the COI management of the researcher's organization, there is a case where other researches implemented by the researcher's organization are individually confirmed.